

Attorney Docket No. 9448-16CT2

In re: Hill et al.

Serial No.: 10/628,057

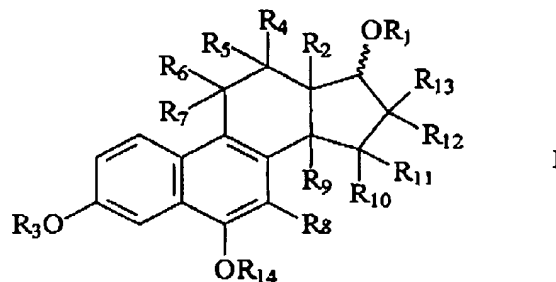
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This listing of the claims will replace all prior versions and listings of the claims in the application:

Listing of the Claims:

1. (Currently Amended) A compound represented by Formula I:



wherein:

the bond represented by the wavy line may be a single or double bond such that when the wavy line is a single bond, R₁ is selected from the group consisting of hydrogen, sulfate and glucuronide ~~glucuronate~~ or other esters, and when the wavy line is a double bond, R₁ does not exist;

R₂ is lower alkyl;

R₃ is selected from the group consisting of hydrogen, sulfate, glucuronide ~~glucuronide~~ or a conjugate thereof;

R₄ through R₇ and R₁₀ through R₁₃ may be the same or different and each represents hydrogen, hydroxy, ketone, lower alkyl, lower alkoxy, halogen, or carbonyl group;

R₈ and R₉ are independently selected from the group consisting of hydrogen, hydroxy, lower alkyl, lower alkoxy, halogen, and carbonyl groups; and

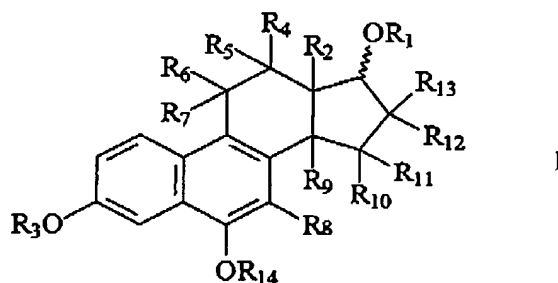
R₁₄ is selected from the group consisting of hydrogen, sulfate, glucuronide ~~glucuronide~~ or a conjugate thereof;

(c) said compound being present in chemically pure form.

2-3. (Canceled)

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4. (Original) The compound according to Claim 1, wherein said compound is greater than about 95% pure.
5. (Original) The compound according to Claim 1, wherein R_2 is C_1 to C_4 alkyl, R_4 - R_{12} are hydrogen and R_{13} is hydrogen or ethynyl.
6. (Previously Presented) The compound according to Claim 1, wherein when R_1 is hydrogen, the compound has a β orientation at the C17 position.
7. The compound according to Claim 1 in conjugated form.
- 8-9. (Canceled)
10. (Currently Amended) A pharmaceutical composition incorporating a compound represented by Formula I:



wherein:

the bond represented by the wavy line may be a single or double bond such that when the wavy line is a single bond, R_1 is selected from the group consisting of hydrogen, sulfate and glucuronide ~~glucuronate~~ and other esters, and when the wavy line is a double bond, R_1 does not exist;

R_2 is lower alkyl;

R_3 is selected from the group consisting of hydrogen, sulfate, glucuronide ~~glucuronide~~ or a conjugate thereof;

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R_4 through R_7 and R_{10} through R_{13} may be the same or different and each represents hydrogen, hydroxy, ketone, lower alkyl, lower alkoxy, halogen, or carbonyl group;

R_8 and R_9 are independently selected from the group consisting of hydrogen, hydroxy, lower alkyl, lower alkoxy, halogen, and carbonyl groups; and

R_{14} is selected from the group consisting of hydrogen, sulfate, glucuronide ~~glucoronide~~ or a conjugate thereof;

said compound being present in chemically pure form.

11-12. (Canceled)

13. (Original) The pharmaceutical composition according to Claim 10, wherein said compound is greater than about 95% pure.

14. (Original) The pharmaceutical composition according to Claim 10, wherein R_2 is C_1 to C_4 alkyl, R_4 - R_{12} are hydrogen and R_{13} is hydrogen or ethynyl.

15. (Previously Presented) The pharmaceutical composition according to Claim 10, wherein when R_1 is hydrogen, the compound has a β orientation at the C17 position.

16. (Original) The pharmaceutical composition according to Claim 10, wherein said compound is in conjugated form.

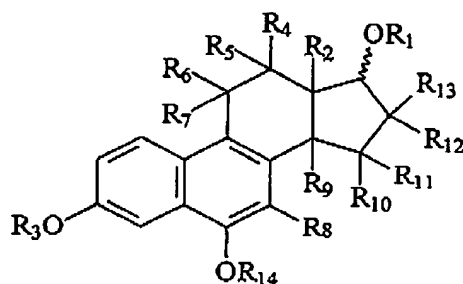
17. (Original) The pharmaceutical composition according to Claim 10, wherein the composition further comprises at least one additional pharmaceutically active ingredient.

18. (Previously Presented) The pharmaceutical composition according to Claim 17, wherein the at least one additional pharmaceutically active ingredient is selected from the group consisting of estrogenic compounds, androgenic compounds, progestin compounds, vasodilation agents, calcium salts, and vitamin D, and mixtures and combinations thereof.

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19-20. (Canceled)

21. (Currently Amended) A method of treating a subject in need of estrogen therapy, said method comprising administering an effective amount of a compound represented by Formula I:



wherein:

the bond represented by the wavy line may be a single or double bond such that when the wavy line is a single bond, R₁ is selected from the group consisting of hydrogen, sulfate and glucuronide ~~glucuronate~~ or other esters, and when the wavy line is a double bond, R₁ does not exist;

R₂ is lower alkyl;

R₃ is selected from the group consisting of hydrogen, sulfate, glucuronide ~~glucuronide~~ or a conjugate thereof;

R₄ through R₇ and R₁₀ through R₁₃ may be the same or different and each represents hydrogen, hydroxy, ketone, lower alkyl, lower alkoxy, halogen, or carbonyl group;

R₈ and R₉ are independently selected from the group consisting of hydrogen, hydroxy, lower alkyl, lower alkoxy, halogen, and carbonyl groups; and

R₁₄ is selected from the group consisting of hydrogen, sulfate, glucuronide ~~glucuronide~~ or a conjugate thereof;

said compound being present in chemically pure form.

22-23. (Canceled)

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24. (Original) The method according to Claim 21, wherein said compound is greater than about 95% pure.

25. (Original) The method according to Claim 21, wherein R_2 is C_1 to C_4 alkyl, R_4 - R_{12} are hydrogen and R_{13} is hydrogen or ethynyl.

26. (Previously Presented) The method according to Claim 21, wherein when R_1 is hydrogen, the compound has a β orientation at the C17 position.

27. (Original) The method according to Claim 21, wherein said compound is in conjugated form.

28. (Original) The method according to Claim 21, wherein said compound is administered as part of a pharmaceutical composition, said composition further comprising at least one additional pharmaceutically active ingredient.

29. (Previously Presented) The method according to Claim 28, wherein the at least one additional pharmaceutically active ingredient is selected from the group consisting of estrogenic compounds, androgenic compounds, progestin compounds, vasodilation agents, calcium salts, and vitamin D, and mixtures and combinations thereof.

30-31. (Canceled)

32. (Previously Presented) The method according to Claim 21, wherein the condition treatable by estrogen therapy is selected from the group consisting of vasomotor symptoms, atrophic vaginitis, osteoporosis, hypoestrogenism due to hypogonadism, hypoestrogenism due to castration, hypoestrogenism due to primary ovarian failure, breast cancer in selected persons with metastatic disease, advanced androgen-dependent carcinoma of the prostate, abnormal uterine bleeding, and kraurosis vulvae.

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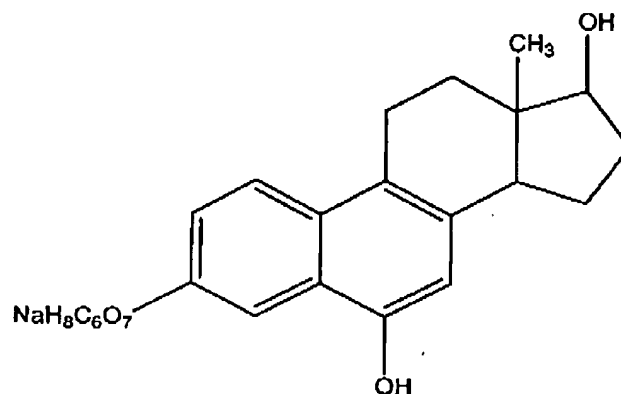
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33. (Previously Presented) A compound represented by the following Formula:

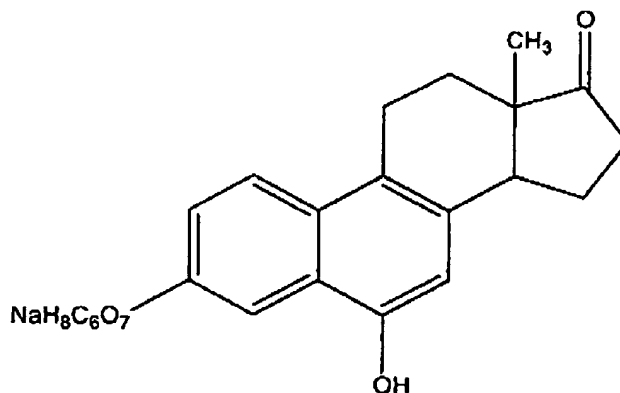


or a pharmaceutically acceptable salt thereof; and said compound has the following physicochemical properties:

having a peak located at about 1.2 ppm on a ¹H-NMR; and

having a peak located at about 45 ppm on a ¹³C-NMR.

34. (Previously Presented) A compound represented by the following Formula:



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or a pharmaceutically acceptable salt thereof; and said compound has the following physicochemical properties:

having a peak located at about 1.2 ppm on a ^1H -NMR; and

having a peak located at about 45 ppm on a ^{13}C -NMR.

35-36. (Canceled)